



DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

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PHILADELPHIA DISTRICT

900 U.S. Courthouse
8th and Chestnut Streets
Philadelphia, PA 19106
Telephone: 215-597-4300

December 2, 1996

Warning Letter

97-PHI-04

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Scott J. Myers, Owner
Chez Bon Incorporated
325 Mt. Lebanon Blvd.
Pittsburgh, PA 15234

RELEASE

Reviewed by: [Signature] 12/11/96
C.O. DATE

F# _____ GEN. ☒ SPEC. ☐

Dear Mr. Myers:

The Food and Drug Administration has reviewed the label for your Water, Rye, High Fiber, Cinnamon-Raisin, Pumpernickel, Blueberry, Honey/Whole Wheat, Honey/Oat Bran, Apple/Bran, Marble, and Garden/Vegetable bagels collected during an October 28, 1996 inspection of your bakery. Based on this review we have determined that these products are in violation of the Food, Drug, and Cosmetic Act (Act) and Title 21 Code of Federal Regulations (CFR) Part 101 as follows:

The products are misbranded under Section 403(q)(1) of the Act in that they fail to bear nutrition labeling as required by 21 CFR § 101.9, and are not exempt under section 403(q)(5) from this requirement because the label includes claims that the product has no cholesterol. Furthermore, the statement of identity for the High Fiber bagels is a nutrient content claim for fiber.

We also note that while three quantity of contents statements appear on the plastic bags used for retail distribution of bagels, there is no means of identifying the actual quantity of contents for the particular food in the package. The net quantity of contents should be declared in metric units as well as inch-pound units. Although FDA has not published final regulations on how the declaration is to be made, the Agency recommends that if a firm wishes to avoid having to change labels again when the metric regulations become effective, it should add the net quantity of contents statement in metric now, using the guidance provided in the proposed regulations in the Federal Register of December 21, 1993.

This is not meant to be an all-inclusive listing of all the deficiencies found in your food labels. It is your responsibility to ensure that all your products are labeled in compliance with the FD&C Act.

Several publications are available to assist you in making the required labeling corrections and in determining if additional corrections are required. The publications include the Code of Federal Regulations (CFR), and a booklet entitled "A Food Labeling Guide." The regulations covering the labeling of foods are found in 21 CFR volume 100 to 169. This book can be obtained from the government book store located at Room 118 Federal Building, 1000 Liberty Ave., Pittsburgh, PA. It can also be ordered by phoning the bookstore at (412) 644-2721. For your convenience we have enclosed a order form for the Food Labeling Guide. You may also elect to use a consultant to assist you in revising your labels.

You should take prompt action to bring your labeling into compliance with current regulations. Please notify this office in writing within fifteen (15) working days of your receipt of this letter of the specific steps you have taken. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes seizure and/or injunction. If available, copies of revised labels should be submitted with your response. If corrective action cannot be completed within 15 working days, state the reason for delay and the time within which the correction will be completed. Your reply should be directed to Beatrice Greenberg, Compliance Officer, at the address shown above.

Sincerely,



Diana J. Kolaitis
District Director
Philadelphia District

enclosure

cc: Pennsylvania State Department of Agriculture
Bureau of Foods and Chemistry
2301 North Cameron Street
Harrisburg, PA 17120-9408
Attn: Leroy C. Corbin, Jr., Director
Division of Food Control